UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY, *Petitioner*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, SYNGENTA CROP PROTECTION, LLC, *Intervenor-Respondent.*	)	No. 22-70118

DECLARATION OF MICHAEL GOODIS IN SUPPORT OF EPA'S CROSS MOTION FOR REMAND

I. Background

A. Introduction

1. I, Michael Goodis, declare under penalty of perjury that the following statements are true and correct to the best of my knowledge and belief and that they are based upon my personal knowledge, information contained in the records of the United States Environmental Protection Agency (EPA), and/or information supplied to me by EPA employees under my supervision and in other EPA offices. *See* 28 U.S.C. § 1746.

2. I am the Deputy Director of Programs in the Office of Pesticide Programs (OPP), EPA. I have held this position since March 2022. Prior to becoming the Deputy Director of Programs for OPP, I served as the Acting Deputy Director of Programs for OPP from July 2020 to March 2022. Prior to becoming Acting Deputy Director of Programs for OPP, I served in various positions within OPP since March 1997, including the Director of the Registration Division and the Associate Director of the Pesticide Re-evaluation Division. I have a B.S. in Geological Engineering from South Dakota School of Mines and Technology and a Master's of Science from the Johns Hopkins Whiting School of Engineering in Technical Management.

3. OPP is the office within EPA that regulates the distribution, sale, and use of pesticides in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Part of OPP's responsibility includes implementing the periodic "registration review" of pesticides as required by section 3(g) of FIFRA, 7 U.S.C. § 136a(g). EPA's essential responsibility under registration review is to review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

4. Several divisions within OPP are involved in registration review. The Pesticide Re-Evaluation Division (PRD) is the lead division overseeing the registration review of conventional pesticides[1] that are currently registered under FIFRA, including difenoconazole. PRD develops EPA's regulatory position as to whether such pesticides continue to meet the FIFRA standard for registration. PRD's work is supported by the work of three other divisions. The Environmental Fate and Effects Division (EFED) assesses the environmental fate and ecological risk of pesticides. In this context, "environmental fate" is the life cycle of a chemical (such as a pesticide) after its release into the environment. Part of this responsibility includes evaluating potential effects to species listed as threatened or endangered (listed species) and/or their designated critical habitats under the Endangered Species Act (ESA) often through a Biological Evaluation. Biological Evaluations ("BEs") are written determinations addressing the potential effects of an action under FIFRA that describes the potential effects of this federal action on listed species or their designated critical habitats. If OPP determines that an action "may affect" listed species or their designated critical habitat in its BEs, OPP would then initiate consultation with the National Marine Fisheries Service (NMFS) and/or the U.S. Fish and Wildlife Service (FWS) (collectively, the Services) under the Services' ESA implementing regulations.[2] *See* 50 C.F.R. § 402.14.

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[1] Conventional pesticides are all active ingredients other than biological pesticides (*i.e.*, certain types of pesticides derived from natural materials such as animals, plants, bacteria, and minerals) and antimicrobial pesticides (*i.e.*, pesticides intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or provide certain protections against bacteria, viruses, fungi, protozoa, algae, or slime). Conventional pesticides are generally synthetic chemicals that prevent, mitigate, destroy, or repel any pest or that act as plant growth regulators, desiccants, defoliants, or nitrogen stabilizers.

[2] EPA may consult with one or both of the Services, depending on the listed species at issue. Congress has divided responsibility for implementing the ESA between the U.S. Secretary of the Interior, who is generally responsible for terrestrial species and inland fishes, and the U.S. Secretary

5. The Health Effects Division (HED) is responsible for reviewing and validating data on properties and effects of pesticides, as well as, characterizing and assessing exposure and risks to humans. The Biological and Economic Analysis Division (BEAD) provides pesticide use-related information, information on agronomic practices, and economic analyses in support of pesticide regulatory activities, including ESA evaluations. BEAD develops information about how much, and the way, pesticides are used to help EPA evaluate potential exposures, the need for various pesticides, and the potential agronomic and economic impacts of regulatory options. In addition to registration review, EFED, HED, and BEAD provide support for pesticide registrations, amendments to registrations, and other pesticide regulatory activities, including ESA compliance for many of these actions.

6. In my role as Deputy Director of OPP, among other duties, I am responsible for assisting the Office Director of OPP with the management, coordination, and oversight of national pesticide programs under FIFRA and the ESA, as well as the Federal Food Drug and Cosmetic Act (FFDCA), the amendments to FIFRA and FFDCA by the Food Quality Protection Act (FQPA) of 1996, and the Pesticide Registration Improvement Act (PRIA). I am responsible for assisting the Office Director of OPP with all regulatory activities associated with pesticides, including pesticide registrations, amendments to registrations, and registration review cases. In addition, I am responsible for assisting the Office Director of OPP with the management and operational responsibilities across a full range of programmatic issues, including providing program policy guidance and oversight over OPP's appropriated budget,

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of Commerce, who is generally responsible for marine species and anadromous fish species. 16 U.S.C. §§ 1532(15), 1533(a)(2). The Secretary of the Interior and the Secretary of Commerce have delegated their ESA responsibilities to FWS and NMFS, respectively. 50 C.F.R. § 402.01(b).

resources, personnel, and the implementation of agency policies.

7. This declaration is filed in support of EPA's Response and Cross-Motion for Remand. The purpose of this declaration is to describe EPA's work related to difenoconazole in registration review, including the work that EPA is doing program-wide to better meet its obligations under EPA's current workload and staffing levels, and the steps required for EPA to complete the registration review decision.

B. Statutory and Regulatory Background

8. **FIFRA.** FIFRA, 7 U.S.C. §§ 136–136y, governs the sale, distribution, and use of pesticides. Its principal purpose is to protect human health and the environment from unreasonable adverse effects associated with pesticides. FIFRA generally prohibits the distribution and sale of a pesticide product unless it is "registered" by EPA. *See* 7 U.S.C. § 136a(a). EPA issues a registration to a particular registrant for a particular formula, packaging, and labeling. That registration provides rights only to the registrant.

9. Pesticide registrations are periodically reviewed as part of the registration review program under FIFRA section 3(g), 7 U.S.C. § 136a(g). For pesticides like difenoconazole that were registered before 2007, the statutory deadline for completing the initial registration review is October 1, 2022. 7 U.S.C. § 136a(g)(1)(A)(iii)(I).

10. EPA regulations set forth the procedures for registration review. *See* 40 C.F.R. part 155. They provide that a "registration review decision" is EPA's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA. *Id.* § 155.57. The regulations also allow EPA to issue, when it determines it to be appropriate, an "interim registration review decision" before completing a registration review. *Id.* § 155.56. Among other things, a

registration review decision or interim registration review decision contains EPA's findings with respect to the FIFRA registration standard and identifies risk mitigation measures and other remedies as needed. *Id.* § 155.58(b). EPA must propose and take public comment on a registration review decision or interim registration review decision before finalizing it. *Id.* § 155.58(a).

11. **EPA Workload**. Difenoconazole is one of 726 registration review cases, which cover 1,100 pesticide active ingredients and for which FIFRA has required EPA to complete initial registration review by October 1, 2022.[3] Of those 726, PRD—with the support of EFED, HED, and BEAD, as described in paragraph 4 and 5—has responsibility for overseeing registration review for 461 cases for conventional pesticides, including difenoconazole.

12. Each registration review case, for a conventional pesticide requires an estimated 8.5 full-time equivalents (FTEs), or workers to complete.

13. EPA estimates that since 2005, the number of pesticide actions before the Agency has ranged from 10,000 to 20,000 per year. However, since 2005, OPP has experienced an approximately 30 percent decline in staffing levels, to the current total of approximately 600 FTEs. These FTEs carry out all regulatory activities associated with all pesticides, including pesticide registrations, amendments to registrations, and registration review cases, as well as ESA compliance for many of these actions. In addition to the statutory deadline for registration review cases, many of these other actions have their own statutory deadlines. *See generally* 7 U.S.C. § 136w-8.

[3] A registration review case may be composed of one or more active ingredients and includes all of the pesticide products containing those active ingredients. Pesticides are grouped into a case when they are closely related or similar in toxicity. *See* 40 C.F.R. § 155.42(a).

14. In light of this significant workload and these resource constraints, EPA has issued interim registration review decisions for many pesticides, including difenoconazole, in order to move forward with aspects of the registration review that are complete and implement interim risk mitigation measures before completing registration review, which is a time-consuming process that includes ESA compliance. Of the 461 conventional pesticides in the initial round of registration review, EPA has issued more than 280 interim registration review decisions and more than 80 final registration review decisions, completed more than 400 proposed interim registration review decisions, conducted more than 450 human health and ecological draft risk assessments (excluding endangered species assessments), imposed risk mitigation measures for nearly 70 percent of pesticides for which EPA issued an interim or final registration review decision, and cancelled some or all uses of more than 80 pesticides.

C. Difenoconazole Interim Registration Review Decision Background

15. In April 2022, EPA published its Interim Registration Review Decision for difenoconazole (Interim Decision) under FIFRA section 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.56. It explained that EPA issued the Interim Decision so that it could move forward with aspects of difenoconazole's registration review that were complete and implement interim risk mitigation measures, and it acknowledged that EPA had other work left to do. Among other things, the Interim Decision summarized the Agency's 2020 Draft Human Health Risk Assessment and 2020 Preliminary Ecological Risk Assessment for registration review for difenoconazole. [Ex. 1 at 13 and 18]. Application of triazole-containing pesticides, such as difenoconazole, also result in exposure to triazole metabolites, which are considered

toxicologically different from difenoconazole and are assessed separately from the parent compound. The 2020 Triazole Risk Assessment[4] conducted to support the 2020 Difenoconazole Draft Human Health Risk Assessment addressed uncertainties related to data gaps in the toxicological database for triazole metabolites by retaining a 10X database uncertainty factor, as established in the 2006 Triazole Risk Assessment. [Ex. 3 at 65]. The Interim Decision included instructions for registrants to submit product label amendments with the specified mitigation measures. [Ex. 1 at 35.]

16. Shortly after publication of the Interim Decision, EPA was notified by registrants of certain errors in the Interim Decision related to seed-treatment labeling language. For example, in Appendix B: Labeling Changes for Difenoconazole Products, EPA duplicated certain language applicable to seed bag/container labeling and misplaced quotations on certain labeling that were intended to be instructions for the registrant. [Ex. 1 at 42.]

17. In response, on June 9, 2022, EPA sent correspondence to all registrants informing them of the errors in the Interim Decision and extending the deadline for submission of amended labels for products containing directions for seed treatment use until such errors could be corrected.[5] As of September 29, 2022, 44 of 83 labels for which mitigation measures were required have been submitted.

18. On June 13, 2022, the Petitioner filed a Petition for Review challenging the Interim Decision. The Petitioner's Motion for Summary Vacatur filed on September 1, 2022, raised EPA's ESA Section 7 consultation duties and allegations that EPA

[4] Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address the Establishment of a Difenoconazole Tolerances with no U.S. Registration for Imported Olive and Black Pepper and to include updated Estimated Drinking Water Concentrations (September 14, 2020).

[5] *Difenoconazole Label Letter to Registrants June 2022*, EPA-HQ-OPP-2015-0401-0067.

failed to obtain requisite studies on human health for metabolites of difenoconazole. In particular, the Petitioner assert that in 2000, EPA issued a data call-in regarding the impact of "1,2,3-triazole[6], a metabolite of difenoconazole, on developmental and reproductive health." The Petitioner further argues that EPA failed to obtain certain studies from the 2000 data call-in and in their absence, cannot support the Interim Decision with substantial evidence as required by FIFRA. As for the requested relief, the Petitioner requested that the Court remand with vacatur of the Interim Decision.

19. EPA has examined the 2006 Triazole Risk Assessment for the triazole metabolites Petitioner attached in support of its Motion for Summary Vacatur along with other files, and upon investigation, EPA has not been able to identify a formal data call-in being issued for 1,2,4-triazole, as Petitioner describes. Rather, EPA's records indicate the Agency sent a letter to the U.S. Triazole Task Force in December 2002 following a meeting between the Task Force and EPA whereby the Agency expressed the need for additional information before an assessment analyzing the potential risks associated with exposure to 1,2,4-triazole and its conjugates could be conducted. In completing the 2006 Triazole Risk Assessment, EPA addressed uncertainties related to data gaps in the toxicological database for triazole metabolites by retaining a 10X database uncertainty factor. To further confirm the findings of EPA's investigation, the Agency inquired on September 9, 2022, with the Task Force as to whether registrants had record of the 2000 data call-in referenced in Petitioner's Motion and the Task Force had no record of a formal data call-in issued in 2000.

[6] While Petitioner refers to "1,2,3-triazoles" in its brief, the 2006 risk assessment references "1,2,4-triazole and its conjugates," and we assume that Petitioner merely mis-cited the name of the metabolite of difenoconazole.

20. Regardless of the events leading to the 2006 Triazole Risk Assessment completed in February of that year, the assessment details the definitive list of outstanding studies on human health in question as Petitioner tacitly acknowledged in its Motion for Summary Vacatur. EPA's records further indicate that, as explained in a December 2006 memorandum, the Agency determined that one of the studies required in the 2006 Triazole Risk Assessment related to acute neurotoxicity in rats for 1,2,4-triazole is no longer needed.[7]

21. While EPA asserts that no formal data call-in was issued in 2000 regarding the impact of 1,2,4-triazole, EPA nevertheless acknowledges that not all of the studies referenced in the 2006 Triazole Risk Assessment were received prior to issuing either the 2006 Triazole Risk Assessment or its 2020 Difenoconazole Draft Human Health Assessment. EPA completed these conservative and protective human health assessments and will re-examine whether there are any outstanding data needs related to the registration review of difenoconazole products upon remand and withdrawal of the Interim Decision.

II. Planned Administrative Action for Voluntary Remand.

22. As set forth in EPA's Cross-Motion for Remand, EPA is seeking a voluntary remand to withdraw the difenoconazole Interim Decision in order to reconsider certain aspects of that the Interim Decision related to arguments raised in the Petitioner's opening brief. EPA intends to promptly withdraw the Interim Decision and anticipates withdrawing the ID within 30 days of the Court issuance of the mandate granting its motion for remand.

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[7] *See* U.S. EPA Memorandum: Waiver Request for Acute Neurotoxicity Study, (December 14, 2006), https://www3.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-113961_14-Dec-06_a.pdf

23. EPA intends to reconsider the issue of outstanding data gaps in the toxicological database for the 1,2,4-triazole metabolite and its conjugates of concern, triazole alanine and triazole acetic acid, related to human health, as raised by the Petitioner and evaluate whether any additional data are required to support future registration review decisions for difenoconazole products. In addition to reconsideration of any outstanding data needs, withdrawal of the Interim Decision will also allow EPA to issue a corrected label table pursuant to future registration review decisions.

24. Ultimately, EPA intends to complete registration review for difenoconazole with the issuance of a final registration review decision, including meeting its ESA obligations.

25. At this time, EPA has not initiated work on a Biological Evaluation for difenoconazole. As noted above, EPA has a very limited number of resources for evaluating pesticides and endangered species effects. Also as noted above, once EPA determines when it can initiate work on difenoconazole, i.e., to conduct ESA analyses and prepare a final biological evaluation, it is likely that it will take two years to complete these steps using the existing ESA method for registration review. If the BE indicates that difenoconazole is likely to adversely affect listed species or designated critical habitat, EPA will initiate formal consultation with the Services, during which time the Services will prepare a Biological Opinion. As demonstrated in the ESA Workplan, this work can take four or more years to complete.

26. Since this ESA consultation must be completed prior to issuing a final registration review decision and since the time for EPA to complete ESA consultation for difenoconazole is likely to take more than four years, the Agency likely will not be able to issue a final registration review decision for difenoconazole for several years.

27. As explained above, EPA cannot set a deadline for its final registration review decision for difenoconazole. It is important that EPA be given time to complete its BE and work with the Services to complete consultation and implement any necessary mitigation measures that come out of that process.

III. Conclusion

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

MICHAEL GOODIS Digitally signed by MICHAEL GOODIS Date: 2022.10.03 16:28:36 -04'00', October 3, 2022

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